FEB 2 0 2001

510(k) Summary K003470

Submitter: Tuttnauer USA Co. Ltd.
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Ronkonkoma, NY 11779

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Contact Name: Robert R. Basile

Date Prepared: November 3, 2000

Common Name: Electronic pre-vacuum autoclave, table-top steam sterilizer

Trade Name: Tuttnauer EHS Series Table-Top Autoclave

Classification Name: Steam Sterilizer
Class II Device - 21 C.F.R. § 880.6880

Substantial Equivalence:

The Tuttnauer Mini Container and Standard Case Cassettes are substantially equivalent to the following currently marketed sterilization cassettes:

Company	Product Name	510(k) Clearance Number
Tuttnauer USA Co. Ltd.	EPV Series Pre-vacuum Autoclave	K962282
Tuttnauer USA Co. Ltd.	E Series Electronic Autoclave	K920478

General Description:

The Tuttnauer EHS Series Table-top Autoclave is a steam sterilizer that provides an onboard steam generation capability. It is designed for sterilization of medical and dental instruments (wrapped and unwrapped), including complex lumened devices (such as dental handpieces), porous, hollow loads and to sterilize liquids for non-clinical applications. The sterilization medium is steam, which is directly introduced into the sterilization chamber. This eliminates the need to wait for water introduced into the chamber to boil and reach sterilization parameters.

Intended Use:

The Tuttnauer EHS Series Table-top Autoclave is intended to provide sterilization of medical and dental instruments (wrapped and unwrapped) including complex lumened devices such as dental handpieces, porous, hollow loads and to sterilize liquids for non-clinical applications.

Technological Characteristics:

The Tuttnauer EHS Series Electronic Table-top Autoclave is a steam sterilizer that includes as its main components: a pressure vessel with steam jacket, heating elements, a dual-chamber water reservoir, a water pump and a vacuum pump. The device is essentially the same as the predicate devices with the exception of: the components necessary for on-board steam generation (as well as the minor change to the software bringing the temperature control into compliance with ANSI/AAMI standards, and the increase to the automated program cycle times). The following table contains a comparison of the characteristics of the device and its predicates.

Characteristic	**EHS Series**	**EPV Series K962282**	**E Series K920478**
Labeling/Intended Use	Auto Steam Autoclave	Auto Steam Autoclave	Auto Steam Autoclave
Process Parameters	Sterilization cycle defined by time, temp. and pressure	Sterilization cycle defined by time, temp. and pressure	Sterilization cycle defined by time, temp. and pressure
Process Monitors	Temp. and pressure gauges, digital display screen, and printer	Temp. and pressure gauges, digital display screen, and printer	Temp. and pressure gauges, digital display screen, and printer
Pre-Vacuum	Yes	Yes	No
On-Board Steam Generation	Yes	No	No
Control	Cycle time, temp., pressure, and user interface controlled by microprocessor	Cycle time, temp., pressure, and user interface controlled by microprocessor	Cycle time, temp., pressure, and user interface controlled by microprocessor
Program Comparison	Wrapped, unwrapped, and dry	Wrapped, unwrapped, liquids, and dry	Wrapped, unwrapped, liquids, and dry
Process Equivalent Times	Sterilization times of 3.5, 8, or 30 minutes depending upon program selected	Sterilization times of 3, 7, or 30 minutes depending upon program selected	Sterilization times of 3, 7, or 30 minutes depending upon program selected

Non-Clinical Testing:

Tuttnauer conducted validation studies in accordance with ANSI/AAMI ST55 (for EHS 2540) and ANSI/AAMI ST8 (for EHS 3870). Successful sterilization was accomplished in all tests performed .

Conclusion:

It is Tuttnauer USA Co. Ltd.'s conclusion that the Tuttnauer EHS Series Table-Top Autoclave is substantially equivalent to its predicate devices. Based upon test data submitted, the Model EHS provides effective sterilization of instruments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2001

Tuttnauer Company Limited
C/O Mr. Mark Yacura
Consultant
Bucanan Ingersoll, P.C.
1776 K Street Northwest
Suite 800
Washington, DC 20006-2365

Re: K003470
Trade Name: Tuttnauer EHS Series Table-Top Autoclave (Models 2540 and 3870)
Regulatory Class: II
Product Code: FLE
Dated: February 8, 2001
Received: February 8, 2001

Dear Mr. Yacura:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K003470

Device Name: Tuttnauer EHS Series Table-Top Autoclave

Indications For Use: The Model EHS is intended to provide sterilization of medical and dental instruments (wrapped and unwrapped), including complex lumened devices such as dental handpieces, porous, hollow loads, and to sterilize liquids for non-clinical applications. It has the following automated program sterilization cycles:

Program 1 (Unwrapped Flash - 273°F)

For sterilization of a single, unwrapped instrument, including a dental handpiece, when the manufacturer recommends autoclaving at temperatures of up to 273°F. No drying cycle is required.

Parameters:

- Sterilization temperature & Range: 273°F (273-279°F)
- Sterilization time: 3.5 minutes
- Pressure & Range: 305 Kpa (305-330 Kpa)

Program 2 (Wrapped Dry - 273°F)

For wrapped instruments and materials, including dental handpieces, which the manufacturer recommends autoclaving at temperatures of up to 273°F with drying cycle.

Parameters:

- Sterilization temperature & Range: 273°F (273-279°F)
- Sterilization time: 8 minutes
- Dry time: 20 minutes
- Pressure & Range: 305 (305-330 Kpa)

Program 3 (Wrapped Dry - 250°F)

For sterilization of wrapped instruments and materials which the manufacturer recommends autoclaving at temperatures of up to 250°F with drying cycle.

Parameters:

- Sterilization temperature & Range: 250°F (250-256°F)
- Sterilization time: 30 minutes
- Dry time: 20 minutes
- Pressure & Range: 205 (205-225 Kpa)

Program 4 (Bowie-Dick Test)

This is a test program, with fixed sterilization parameters of 273°F and 3.5 minutes which cannot be modified by the operator.

Parameters:

- Sterilization temperature & Range: 273°F (273-279°F)
- Sterilization time: 3.5 minutes
- Dry time: 2 minutes
- Pressure & Range: 305 (305-330 Kpa)

Program 5 (Vacuum Test)

The vacuum pump is activated until the vacuum reaches a value of at least 40 kPa (400 mbr) (20 kPa nominal). All the valves and pump shut down (P1). The following 5 minutes is for the stabilization condition of the chamber (P2). From now on (P2) along the next 10 minutes the allowable decrease of pressure is 0.13 kPa/minute (or 1.3kPa for 10 minutes).

During the entire test period the decline rate of the vacuum should not exceed 0.13kPa/minute.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over -The-Counter Use X

(Per 21 C.F.R. § 801.109)

(Optional Format 1-2-96)

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003470